

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY |) | MDL No. 1456 |
| AVERAGE WHOLESALE PRICE |) | Master File No. 01-12257-PBS |
| LITIGATION |) | |
| _____ |) | (Original Central District of California |
| |) | No. 03-CV-2238) |
| THIS DOCUMENT RELATES TO: |) | |
| State of California, <i>ex rel.</i> Ven-A-Care v. |) | Judge Patti B. Saris |
| Abbott Laboratories, Inc., <i>et al.</i> |) | |
| CASE #: 1:03-cv-11226-PBS |) | |
| _____ |) | |

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' OBJECTIONS PURSUANT TO RULE
201(e) OF THE FEDERAL RULES OF EVIDENCE TO JUDICIAL NOTICE OF FACTS
AND CONCLUSIONS SET FORTH IN DEFENDANTS' MOTION TO DISMISS**

In their Motion to Dismiss, Defendants asked the Court to take notice of a handful of publicly-available documents. These documents belie the crux of Plaintiffs' claims -- that California was somehow duped into reimbursing pharmaceutical drug costs at an inflated level. Unable to escape the import of these documents, California begs this Court to ignore these crucial documents. (*See* Pls. Objs. at 2-3.) California's plea, however, is legally unsound. This Court has both the right and the duty to take judicial notice of these documents. FED. R. EVID. 201(b)&(d). Nor do Plaintiffs seriously contend otherwise. Indeed, in their Objections, Plaintiffs make only one legal argument in opposition to judicial notice of Defendants' exhibits - that the exhibits contain purportedly disputed facts.¹ The argument is without merit, though, as

¹ Plaintiffs' remaining arguments are irrelevant to the question of whether it is appropriate for the Court to take judicial notice of these exhibits. Plaintiffs argue that California's knowledge of the difference between AWP and Direct Price and providers' actual acquisition costs is irrelevant to this case, and that the Court should not draw any inferences from California's decision, in light of that knowledge, to continue to reimburse providers in excess of the amount for which the providers acquired Defendants' drugs. These arguments should have been included in Plaintiffs' opposition to Defendants' Motion to Dismiss. Indeed, the inclusion of these arguments in the Objections gives the distinct impression that Plaintiffs really only filed the Objections to circumvent CMO 18's 40-page limit -- especially since Plaintiffs used every single page of that limit in their Response.

Plaintiffs do not (and cannot) offer a single specific example of a disputed fact in the exhibits.²

Plaintiffs' Objections should be overruled and Defendants' request for judicial notice should be granted.

ARGUMENT

Not only *may* a court take judicial notice of facts that are “not subject to reasonable dispute,” but indeed, a court is *required* to take such judicial notice when, as here, a party requests that the court take judicial notice and supplies the court with the necessary information. FED. R. EVID. 201(b)&(d). Courts have repeatedly found that it is appropriate to take judicial notice of matters on Rule 12(b)(6) motions without converting such motions to motions for summary judgment. *See MGIC Indem. Corp. v. Weisman*, 803 F.2d 500, 504 (9th Cir. 1986) (“On a motion to dismiss, we may take judicial notice of matters of public record outside the pleadings”); *In re Vertex Pharm, Inc.*, 357 F. Supp. 2d 343, 352 n.4 (D. Mass. 2005) (Saris, J.) (taking judicial notice of FDA policy on website when considering Rule 12(b)(6) motion); *Koelsch v. Town of Amesbury*, 851 F. Supp. 467, 499 (D. Mass. 1994) (Saris, J.) (noting that the Court may consider matters of public record in determining whether to grant a Rule 12(b)(6) motion).

Moreover, government reports and state records, like those offered by Defendants here, are precisely the type of documents that are appropriate for judicial notice.³ *See Wilbur v. Locke*, 423 F.3d 1101, 1112 (9th Cir. 2005) (taking judicial notice of a state contract that is a matter of public record); *Lamers Dairy Inc. v. USDA*, 379 F.3d 466, 471 n.8 (7th Cir. 2004) (taking judicial notice of reports issued by the USDA); *Mack v. South Bay Beer Distrib.*, 798 F.2d 1279,

² Plaintiffs' arguments on pages 4-6 of their Objections concern only what *conclusions* can be drawn from the facts contained in the exhibits.

³ Plaintiffs do not appear to be objecting to the Court taking judicial notice of Exhibits B and C.

1282 (9th Cir. 1986) (taking judicial notice of California administrative records); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 755 (E.D. Pa. 2003) (stating that it is appropriate to take judicial notice of public records, which include published reports of administrative bodies).

Finally, it is appropriate for courts to infer a party's knowledge about events from judicially noticed facts. *See MGIC Indem. Corp.*, 803 F.2d at 504-05 (taking judicial notice of memorandum filed in another case and concluding from the contents of that memorandum that plaintiff was fully aware of defendants' actions); *Andrews-Clarke v. Travelers Ins. Co.*, 984 F. Supp. 49, 64 (D. Mass. 1997) (taking judicial notice of the existence of bills in Congress to conclude that Congress was aware of "the gap in remedies" available to patients who are wrongfully denied insurance benefits).

In light of these clear legal principles, Plaintiffs' Objections fail.

I. DEFENDANTS' EXHIBITS ARE NOT SUBJECT TO REASONABLE DISPUTE.

Plaintiffs' sole attempt to avoid judicial notice is to claim that Defendants seek judicial notice of "disputed facts." Not so -- indeed, none of the facts of which Defendants seek judicial notice is subject to reasonable dispute. All of the documents Defendants have offered are either (1) reports issued by government agencies or (2) documents found in California regulatory history.

At bottom, Plaintiffs appear confused about Defendants' request for judicial notice. Defendants are *not* asking the Court to assume that *every fact* contained in the exhibits is true. Rather, Defendants ask the Court to take judicial notice that the documents exist, when they existed, and of certain things they contain -- regardless of whether these things are ultimately "true." That is entirely appropriate; even Plaintiffs' authorities hold no differently. *See Lee v. Los Angeles*, 250 F.3d 668, 689-90 (9th Cir. 2001) (stating that the district court had the

authority “to take judicial notice of the fact of the extradition hearing, the fact that a Waiver of Extradition was signed by Kerry Sanders, and the fact that Kerry Sanders purportedly waived his right to challenge his extradition to New York as ‘Robert Sanders’” but erred in taking judicial notice of “the *validity* of the Waiver of Extradition”) (emphasis added).⁴

Specifically, Defendants are asking the Court to take judicial notice of specific documents from the public record that demonstrate *awareness* on the part of California regarding the relationship between AWP and Direct Price and providers’ acquisition costs. This is a far cry from the judicial notice rejected in both *Hoyt Cinemas Corp.* and *New Alliance Party*. See *United States v. Hoyt Cinemas Corp.*, 380 F.3d 558, 569 (1st Cir. 2004) (rejecting the trial court’s sua sponte judicial notice (without citation to any document or authority) that movie patrons prefer the middle or back of the theater); *New Alliance Party v. N.Y. State Bd. of Elections*, 861 F. Supp. 282, 292 (S.D.N.Y. 1994) (declining to take judicial notice of the existence of “position bias” where its existence was not commonly held knowledge and no public record was offered for its support).

For instance, Exhibit A is a report from May 1996 issued by the Department of Health and Human Services, Office of Inspector General (“OIG”), which found that California pharmacies routinely obtain brand name drugs at AWP-17.5% and generic drugs at AWP-41.4%. (May 31, 1996 letter from Inspector General to HCFA, Ex. A.) Attached as Appendix 4 to this

⁴ *Carley* is also not contrary. In *Carley*, the appellate court found that the district court could take judicial notice, based on common knowledge, of the fact that the government performs various tests on vehicles, but that the “quantity and nature of those tests are not matters of common knowledge, nor are they readily provable through a source whose accuracy cannot be questioned.” *Carley v. Wheeled Coach*, 991 F.2d 1117, 1126 (3rd Cir. 1993). Here, unlike in *Carley*, Defendants ask the court to take judicial notice of a specific government report in the public record -- not facts that are common knowledge. Moreover, Defendants are not asking the Court to take judicial notice of any scientific testing methods contained in any reports, but simply the existence of the reports, themselves; *Carley* is thus easily distinguished. Plaintiffs’ remaining authorities are equally easily dispatched because Defendants are not asking the Court to take judicial notice of sweeping conclusions, but rather, of narrowly defined propositions supported by specific exhibits.

report is a letter from John Rodriguez, California Department of Health Services, commenting on the OIG findings and stating:

DHS intends to use these results, when published in the final report, to support a provision of our Governor's budget proposal to decrease drug ingredient reimbursement. *The audit results will, hopefully, substantiate DHS' position that current drug ingredient cost reimbursement by the Medi-Cal program does not reflect actual purchasing activity of California pharmacies.*

(App. 4, Ex. A) (emphasis added).

It is indisputable that this OIG report exists, that it existed in 1996, and that the OIG alerted California that it had found that California pharmacies routinely purchased drugs for far less than the amounts that Medi-Cal was reimbursing for the cost of the drugs. Moreover, it is indisputable that California responded by acknowledging that Medi-Cal was not reimbursing pharmacies at actual acquisition costs. The only logical conclusion is that in 1996, when Medi-Cal was reimbursing pharmacies at AWP-5% or Direct Price, Medi-Cal was aware that government reports found that AWP-5% and Direct Price did not approximate pharmacies' acquisition costs. Yet California continued to pay these alleged "false" claims using those reimbursement levels.

California does not dispute the existence of the documents, or even the facts contained in the documents. Instead, Plaintiffs argue that this report and California's letter commenting on the OIG audit prove nothing more than "a lack of certainty of pricing." (Pls.' Objs. at 5.) While the *exact* prices at which providers obtained drugs may be uncertain, one thing is not -- in 1996 California had notice that its reimbursement for drugs was significantly in excess of the actual acquisition costs of California pharmacies.

Exhibit D is a memorandum dated July 22, 1976, found in Medi-Cal's regulatory record discussing Medi-Cal's MAIC program. Defendants asked the court to take judicial notice of this

document primarily to show that Medi-Cal's MAIC program has existed since at least the 1970's. (Defs.' Mem. at 9.) Plaintiffs do not dispute this fact, and it is indeed indisputable given the fact that this program's existence is discussed in a document dated in the 1970's.

Exhibit E contains excerpts from price lists obtained from the Medi-Cal regulatory record. These price lists are dated in 1987 and list an AWP and a customer price for various drugs. The listed customer prices are often substantially lower than the listed AWPs. Plaintiffs do not dispute that these are excerpts of documents that were in California's possession. Rather they argue they are irrelevant because (1) they pre-date the allegations in the Amended Complaint and (2) they do not prove that California always had access to provider pricing, knew the exact nature of the spreads, or agreed to the excessive spreads. (Pls.' Objs. at 5.) Plaintiffs' argument is primarily one of relevancy, not the appropriateness of judicial notice.

First, courts have found that it is appropriate to take judicial notice of events prior to the events that occurred during the time period for which plaintiffs are seeking damages to show a pattern of behavior -- in this case California's long-standing awareness of and acquiescence in paying providers significantly more than their actual costs for acquiring drugs. *See In re Netflix, Inc. Sec. Litig.*, 2005, Cause No. C04-2978, U.S. Dist. LEXIS 18765 *14 (N.D. Cal. June 28, 2005) (overruling objections to judicial notice of documents that pre-dated the time period stated in the complaint). Moreover, the regulations and statutes that form the basis of California's suit had their genesis long before 1994. It is appropriate for the Court to take into consideration California's resources when it was deciding how to reimburse providers for prescription drugs.

Second, Plaintiffs' contention that California did not agree to "excessive spreads" is explicitly contradicted by Exhibit F. Notably, Plaintiffs fail to mention Exhibit F in their Objections. Exhibit F is a Final Statement of Reasons from 1987, which lists the pricing sources

(including Exhibit E) that California had in its possession when amending its reimbursement methodology. Additionally, the document has calculations on page 3 of the Addendum that show that California expected that the reimbursement methodology it was adopting would result in spreads between AWP and actual cost of over 100%.

Exhibit G is another OIG report (issued in October 2003), which discusses the OIG findings regarding “State Strategies to Contain Medicaid Drug Costs.” As previously mentioned, government reports are precisely the type of document of which it is appropriate to take judicial notice. *See, e.g., Lamers Dairy Inc.*, 379 F.3d at 471 n.8. Notably, once again Plaintiffs do not specifically dispute any of Defendants’ conclusions drawn from that report.

Finally, footnote 2 on page 6 of Plaintiffs’ Opposition highlights the absurdity of their position. Plaintiffs argue that it is inappropriate for the Court to take judicial notice of the fact that Ven-A-Care’s complaint was initially filed under seal in 1998. Plaintiffs state, “Moreover, Defendants presumably would be the last to argue that this Court should take judicial notice of the facts within the Relator’s sealed allegations.” (Pls. Objs. at 6.) Once again, however, Defendants are not arguing that the facts contained within the relator’s complaint are true, but rather that the complaint actually exists (and existed in 1998) and that the complaint contains allegations that gave California notice back in 1998 of the alleged fraud that California is now claiming was perpetrated by Defendants. Clearly a court can take judicial notice of the existence of a complaint, and the allegations contained therein, without taking judicial notice of the truth of the allegations asserted. *See E.I. du Pont de Nemours & Co., Inc. v. Cullen*, 791 F.2d 5, 7 (1st Cir. 1986) (court may take judicial notice of complaint filed in related case).

II. PLAINTIFFS' ARGUMENT BASED ON GOVERNMENT INACTION IS MISPLACED.

While completely unrelated to the issue of judicial notice, Plaintiffs also argue in their Objections that the Court should not infer any conclusions from the fact that California maintained Medi-Cal reimbursement levels at amounts it knew exceeded providers' costs for acquiring drugs. Plaintiffs' argument is misplaced, and the cases cited are inapposite.

Defendants ask this Court to take judicial notice of their exhibits to show that California had knowledge that Medi-Cal reimbursement exceeded providers' acquisition costs for drugs. The Court does not need to reach any conclusion regarding California's inaction to take judicial notice of this knowledge. California's knowledge alone defeats Plaintiffs' claims under the California False Claims Act. (*See* Defs. Mem. at 22-24; Defs. Reply at 8-10.) California's inaction despite this knowledge is one additional fact that supports the conclusion that California actually intended to reimburse providers at an amount in excess of their acquisition costs for drugs.

Plaintiffs' cases hold no differently. Indeed, not a single case cited by Plaintiffs even addresses the issue of government knowledge or the False Claims Act. Nor do any of these cases hold that legislative inaction can never be considered as *one factor* by a Court in reaching a conclusion. Instead, Plaintiffs string cite a series of cases that address the impact of legislative history on statutory interpretation. *See United States v. Croft*, 535 U.S. 274, 287 (2002) (discussing effect of failed legislative proposals on interpretation of prior statute); *Central Bank of Denver, N.A. v. First Inter-State Bank of Denver, N.A.*, 511 U.S. 164, 186 (1994) (discussing whether congressional failure to act represents approval of the Court's statutory interpretation); *Arnold Tours, Inc. v. Camp*, 472 F.3d 427 (1st Cir. 1972) (discussing statutory interpretation of

National Bank Act); *Commonwealth v. Houston*, 722 N.E.2d 942 (Mass. 2000) (applying familiar principles of statutory interpretation to rape-shield law).

CONCLUSION

For these reasons, the Court should overrule Plaintiffs' Objections, and take judicial notice of the publicly available documents attached to Defendants' Memorandum of Law In Support of Their Motion to Dismiss while considering the merits of Defendants' Motion to Dismiss.

Dated: April 3, 2006

SUBMITTED ON BEHALF OF ALL LISTED
DEFENDANTS BY:

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on April 3, 2006, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Tara A. Fumerton

Tara A. Fumerton